

K111915

DEC - 2 2011

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION

DECISION SUMMARY

DEVICE ONLY TEMPLATE

A. 510(k) Number:

K111915

B. Purpose for Submission:

New Device

C. Measurand:

Magnesium

D. Type of Test:

Quantitative, Photometric Method

E. Applicant:

Sekisui Diagnostics P.E.I. Inc.

F. Proprietary and Established Names:

Magnesium Assay

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1495

2. Classification:

Class I

3. Product code:

JGJ

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

For the IN VITRO quantitative measurement of magnesium in serum and plasma.

2. Indication(s) for use:

The Sekisui Magnesium Assay is for the quantitative determination of magnesium in human serum and plasma (Lithium Heparin) on automated clinical chemistry analyzers. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium). This device is intended for professional use and IN VITRO diagnostic use only.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Clinical chemistry analyzers (testing was performed on the Roche/Hitachi® 717 Automated Analyzer).

I. Device Description:

The Sekisui Magnesium assay kit consists of the following:

Magnesium Reagent: A solution containing buffer (pH 11.2 at 25°C), 0.14 mmol/L xylidyl blue-1, 0.1 mmol/L EGTA, and a surfactant.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Beckman Coulter Magnesium Reagent

2. Predicate 510(k) number(s):

K944407

3. Comparison with predicate:

(Similarities and Differences between the candidate device and the predicate device).

Parameter	Candidate Device	Predicate Device
	Sekisui Diagnostics Magnesium Assay	Beckman Coulter Magnesium Reagent OSR6189 K944407
Analyte	Magnesium	Magnesium
Intended Use	For the IN VITRO quantitative measurement of magnesium in serum and plasma.	System reagent for the quantitative determination of Magnesium in Human serum, plasma and urine on Beckman Coulter AU analyzers.
Sample Matrix	Serum or LiHeparin Plasma	Serum or Heparinized Plasma or urine
Reportable Range	0.3 – 8.0 mg/dL	0.5 -8.0 mg/dL
Reference Interval	1.6-2.6 mg/dL	1.9-2.7 mg/dL
Technology / Methodology	Colorimetric endpoint method using xylidyl blue.	Colorimetric endpoint method using xylidyl blue.
Format	Liquid	Liquid

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP5-A2, Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline

CLSI EP9-A2, Method Comparison and Bias Estimation Using Patient samples; Approved Guideline

CLSI EP17-A, Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline

CLSI C28-A2, How to define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline

L. Test Principle:



Under the alkaline conditions of the Magnesium reagent, magnesium present in the sample, when mixed with reagent, forms a red complex with the diazonium salt of xylidyl blue. The concentration of magnesium in the sample is directly proportional to the amount of xylidyl blue–Magnesium complex formed and can be measured spectrophotometrically by the decrease in absorbance measured at 660 nm.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision testing was performed according to CLSI guideline EP5-A2. Samples, including serum pools and control materials, were tested twice per day in duplicate for 20 days. Results are summarized below:

Precision table for Sekisui Diagnostics Magnesium on Roche Hitachi 717 automated analyzer:

Concentration		Total SD		Total CV %	Concentration		Within Run SD		Within Run CV %
mg/dL	mmol/L	mg/dL	mmol/L		mg/d	mmol/L	mg/d	mmol/L	
0.8	0.33	0.05	0.021	6.1	0.9	0.37	0.06	0.024	7.0
2.0	0.82	0.07	0.029	3.7	2.0	0.82	0.04	0.016	2.2
4.7	1.93	0.15	0.062	3.2	4.9	2.01	0.08	0.033	1.6

b. Linearity/assay reportable range:

A linearity study was performed in accordance with CLSI protocol EP6-A, *Evaluation of the Linearity of Quantitative Measurement Procedures, a Statistical Approach*, and the Sekisui Diagnostics Magnesium method was demonstrated to be linear across the reportable range from 0.2 mg/dL (0.08 mmol/L) to 8.0 mg/dL (3.29 mmol/L). A high concentration serum pool was diluted with saline to produce 11 concentrations of magnesium. Samples were assayed in replicates of four. The results were used to generate best fit regression lines using a linear equation.

Nonlinearity is less than allowable nonlinearity.

Summary of Linear Fit

Slope 1.01

Intercept 0.013 mg/dL

N 11

The linearity testing confirmed a reportable range of 0.3 – 8.0 mg/dL (0.12 – 3.29 mmol/L).

c. Detection limit:

The determination of the method detection limits was performed according to the CLSI EP17-A Guideline, *Protocols for Determination of Limits of Detection and Limits of Quantitation*; Approved Guideline. Limit of Detection (LoD) is defined as the smallest amount of an analyte that the method can reliably detect to determine presence or absence of the analyte. LoD was

determined by measuring 60 replicates of a zero magnesium sample and 60 replicates of the low concentration serum control sample.

The results were used following the EP17-A guidelines to calculate the Limit of Blank (LoB), Limit of Detection, and Limit of Quantitation (LoQ). The Limit of Blank was determined as 0.15 mg/dL magnesium. The Pooled SD for the low values of the samples was determined as 0.06 mg/dL; therefore, the LoD is calculated to be 0.25 mg/L. The LoQ represents the magnesium concentration where the CV is less than or equal to 20%. The LoQ is therefore 0.30 mg/L.

d. Analytical specificity:

Interference studies on the effects of endogenous and exogenous substances were designed according to the CLSI EP7-A2 guideline. Potentially cross-reactive or interfering substances that were evaluated included five endogenous substances (unconjugated bilirubin, conjugated bilirubin, hemoglobin, lipemia, and ascorbic acid). Three samples of human serum with different concentrations of magnesium were tested with the potential interference substances and analyzed in quadruplicate on the Roche Hitachi 717 automated analyzer. No significant interference was defined to be within +/- 10% of the corresponding control result for the high magnesium sample.

Concentration of Analyte		Substance Tested	Concentration of Interferent where Interference is Insignificant	
mg/dL	mmol/L			
2.1	0.86	Hemoglobin	1000 mg/dL	155 µmol/L
4.2	1.73		1000 mg/dL	155 µmol/L
7.9	3.25		1000 mg/dL	155 µmol/L
2.0	0.82	Conjugated Bilirubin	40 mg/dL	684 µmol/L
4.3	1.77		40 mg/dL	684 µmol/L
6.8	2.79		40 mg/dL	684 µmol/L
2.0	0.82	Unconjugated Bilirubin	40 mg/dL	684 µmol/L
4.2	1.73		40 mg/dL	684 µmol/L
6.8	2.79		40 mg/dL	684 µmol/L
2.3	0.95	Ascorbic Acid	3000 µg/dL	170 µmol/L
4.4	1.81		3000 µg/dL	170 µmol/L
6.8	2.79		3000 µg/dL	170 µmol/L
1.9	0.78	Intralipid	800 mg/dL	2400 mg/dL (27.1 mmol/L) Simulated Triglycerides
4.1	1.69		1000 mg/dL	3000 mg/dL (33.9 mmol/L) Simulated Triglycerides
6.9	2.84		1000 mg/dL	3000 mg/dL (33.9 mmol/L) Simulated Triglycerides

e. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed based on the CLSI EP9-A2 guideline. Serum samples (n=100) were obtained for the study, of which 100 were determined to be within the reportable range of the candidate method and the Predicate method (sample recoveries ranged from 0.5 mg/dL to 7.3 mg/dL magnesium). The Beckman Coulter method on the AU640 was used to compare the results performed using the Sekisui Diagnostics Magnesium Assay on the Roche Hitachi 717 automated analyzer. The results demonstrate the Sekisui Diagnostics Magnesium test method on Roche Hitachi 717 is substantially comparable with the Beckman Coulter magnesium assay on AU640 analyzer. A summary of the regression statistics is provided below:

Samples, n= 100

Slope: 0.981
Intercept: 0.00 mg/dL
Correlation: 0.9848

b. Matrix comparison:

A matrix comparison study was conducted using fresh samples from non-fasting donors drawn as serum, and Li Heparin plasma. Sekisui Diagnostics Magnesium method with serum was used to compare the results obtained using the Sekisui Diagnostics Magnesium Assay with plasma on the Roche Hitachi 717 automated analyzer. The results demonstrate the Sekisui Diagnostics Magnesium test method with plasma is substantially comparable with the Sekisui Diagnostics Magnesium test method with serum on Roche Hitachi 717 analyzer. A summary of the regression statistics is provided below:

Samples, n= 54
Slope: 1.009
Intercept: -0.12 mg/dL
Correlation: 0.9903

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Testing followed the CSLI C28-A guideline to validate the reference range using a study of 20 serum samples from apparently healthy donors. The reference range is validated if the samples result in no outliers. The testing did not result in outliers supporting the literature reports of adult reference ranges for magnesium. [Tietz, N.W., (Editor) Clinical Guide to Laboratory Tests, W.B. Saunders Company, Philadelphia (1983) p.338.].

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The information presented in the premarket notification demonstrates that the performance of the Sekisui Diagnostics Magnesium Reagent for use with human serum and lithium heparin plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using patient samples with magnesium values that span the assay range.

The information presented in the premarket notification provides a reasonable assurance that the Sekisui Diagnostics Magnesium for use with human serum and lithium heparin plasma is safe and effective for the stated intended use.



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DEC - 2 2011

Re: k111915
Trade Name: MAGNESIUM ASSAY
Regulation Number: 21 CFR §862.1495
Regulation Name: Magnesium test system
Regulatory Class: Class I, reserved
Product Codes: JGJ
Dated: October 19, 2011
Received: October 24, 2011

Dear Ms. White

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

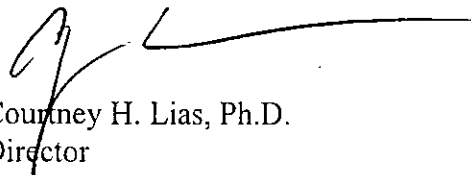
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111915

Device Name: Magnesium Assay

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111915